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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,311	04/11/2006	Nicola Anne Burgess	13001015PCTUS	5452
23565	7590	08/24/2007		
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			EXAMINER GUSSOW, ANNE	
			ART UNIT	PAPER NUMBER
			1643	
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			08/24/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/575,311

Applicant(s)

BURGESS, NICOLA ANNE

Examiner

Anne M. Gussow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9 and 13-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 13-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7, 9, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 8 and 10-12 have been cancelled.  
Claims 7 and 9 have been amended.  
Claims 28 and 29 have been added.
2. Claims 7, 9, 28 and 29 are under examination.
3. The following Office Action contains NEW GROUNDS OF REJECTION.

#### ***Objections Withdrawn***

4. The objections to the specification are withdrawn in view of applicant's amendments to the specification.

#### ***Rejections Withdrawn***

5. The rejection of claims 8-9 and 12 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting the phrases "functionally-active fragment" and "activity of the CDCP1 polypeptide" is withdrawn in view of applicant's amendment to the claims.

#### ***Response to Arguments/NEW GROUNDS OF REJECTION***

##### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7, 9, 28, and 29 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite for reciting the phrase "a CDCP1 polypeptide comprising or consisting of the amino acid sequence of SEQ ID No. 1 or residues 30-667 of SEQ ID No. 1" in claim 7. It is not clear if the polypeptide is comprising or consisting of SEQ ID No. 1 or if the polypeptide is comprising or consisting of residues 30-667 of SEQ ID No. 1.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. The rejection of claims 7, 9, and newly added claims 28 and 29 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained.

The response and accompanying Mason declaration filed July 5, 2007 has been carefully considered but is deemed not to be persuasive. The response states that CDCP1 is a newly identified target for ovarian cancer (see response page 15) and the declaration shows that the antibody to CDCP1 binds to ovarian cancer cells. In response to this argument, while the evidence provided in both the as-filed specification and the declaration demonstrates that CDCP1 is detectable on ovarian cancer cells and

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the CDCP1 antibody binds to the ovarian cancer cells, there is no evidence to suggest that the antibody itself binding to the cell induces cell death, thus providing a treatment for ovarian cancer. The declaration suggests that the anti-CDCP1 antibody could "provide a therapy through recruitment of immune effector mechanisms, modulation of CDCP1 function or via a toxin conjugated antibody" (see declaration page 2). While the examiner agrees with the applicant's argument that recruitment of other molecules or use of a conjugated antibody would provide a therapy to induce cell death, and thus an effective treatment for ovarian cancer, support for the CDCP1 antibody providing an effective treatment was not provided in the specification as-filed, or in the declaration filed July 5, 2007. As set forth in the previous office action, the specification teaches binding and internalization of the anti-CDCP1 antibody to ovarian cancer cells. The specification does not teach whether binding and/or internalization of the antibody/polypeptide complex lead to cell death. Thus, there is insufficient evidence to provide enablement for the unconjugated anti-CDCP1 antibody itself to be effective as an ovarian cancer therapy. Therefore, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

### ***Conclusion***

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

August 20, 2007



LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER